UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

June 6, 2001

Memorandum

SUBJECT: Review of *Determination of Dermal (Hand and Forearm) and Inhalation Exposure to Disulfoton Resulting from Residential Application of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care to Shrubs and Flower Beds*. MRID No.453334-01.
DP Barcode: 273144.

FROM: Shanna Recore, Industrial Hygienist
Reregistration Branch 2
Health Effects Division (7509C)

THRU: Al Nielsen, Branch Senior Scientist
Reregistration Branch 2
Health Effects Division (7509C)

TO: Christina Scheltema, Chemical Review Manager
Reregistration Branch 3
Special Review and Reregistration Division (7508W)

Attached is a review of the dermal and inhalation exposure data submitted by Bayer Corporation. This review was completed by Versar, Inc. on March 20, 2001, under supervision of HED. It has undergone secondary review in HED and has been revised to reflect Agency policies.

Executive Summary

The data collected, reflecting the residential applicator dermal and inhalation exposure of disulfoton, meets most of the criteria specified by the U.S. Environmental Protection Agency's (US-EPA) OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: Application Exposure Monitoring Test Guidelines, 875.1300, Inhalation Exposure -- Outdoor and 875.1100, Dermal Exposure -- Outdoor. The data are of sufficient scientific quality to be used to determine dermal and inhalation exposure pending clarification/response to our outstanding concerns.

Summary

The purpose of this study was to quantify potential dermal (forearm and hand) and inhalation exposure for residential applicators of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care®, a granular formulation, which contains 1.04 percent disulfoton as the active ingredient. Disulfoton is a systemic organophosphate insecticide registered for use on residential ornamentals including rosebushes, shrubs, and flowerbeds. The maximum application rate for flower beds (4 ounces formulated product per 12 square feet) and for shrubs, which includes rosebushes, (4 ounces formulated product per 1 foot shrub height) was used in this study.

The field study was conducted at the Bayer Corporation Research Farm, Vero Beach, Florida. A total of 15 volunteers were monitored using passive dosimetry (hand/forearm wash solutions and personal air monitors). Application of the product was made by pouring the granules into the measuring cup/lid attached to the product package, and then distributing the granules onto the soil around the base of a shrub or onto a flower bed. The granules were then soil-incorporated with a garden rake. Each volunteer applied granular disulfoton around shrubs while wearing gloves and then again without gloves. A total of 60 (i.e., 15 volunteers x 4 exposure scenarios) replicates were monitored. Only exposure data from the 30 replicates who did not wear gloves were reported. The test site was a fallow test field, approximately 1 acre in size. Two sets of sub-plots were established: (1) shrub test-plots, each containing 10 oleander shrubs (approximately 48 inches high); and (2) flower-bed sub-plots, each containing simulated plants, (e.g., 12 to 14 inch high stakes placed on approximately 24 inch centers).

Each volunteer applied approximately 10 pounds of formulated product per application. Shrubs were treated by spreading 16 ounces of granules (i.e., 4 ounces per 1 foot of shrub) in a circle around each shrub's base. The granules were then incorporated into the top 1-2 inches of soil using a new garden rake. Flower beds were treated by sprinkling 4 ounces of granules to each 12 square feet of a total 480 square feet area, and incorporating the product into the top 1-2 inches of soil using a new garden rake.

All of the inhalation exposure data were either non-detect or less than the limit of quantitation (LOQ). Most of the hand/forearm dermal washing samples returned results greater than the LOQ. Disulfoton residues found on the hand and forearm samples collected from monitoring periods where volunteers did not wear gloves were highest when applying Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care® to shrubs. All of the samples collected while subjects treated oleander shrubs were positive, with residue levels ranging from 1.39 to 36 μg/sample (N=15) and with a mean value of 13.5 μg. Ten of 15 samples collected

while subjects treated flowerbeds had results >LOQ, ranging from 1.88 to 20.6 μg/sample with a mean of 5.45 μg. The author speculates "applying and working around the larger plants in the shrub plots, and possibly opening and closing the product container at each shrub increased the hand and forearm exposure as compared to flower bed applications."

The author reported that the time it took to treat shrubs ranged between 18 and 29 minutes. The time that it took to treat flowerbeds ranged between 20 and 40 minutes.

Conclusion

The dermal and inhalation exposure study completed in support of the regulatory requirements contained the following omissions and flaws with respect to Series 875 Group A Application Exposure Monitoring Test Guidelines. The most important discrepancies and issues of concern include: (1) the Agency is particularly concerned with the sleeve length worn by the study participants (i.e. long sleeves vs. short sleeves); however, the clothing worn by each study participant was not thoroughly described, the author stated only that "for the first three sessions, volunteers wore new pairs of Tyvek® pants over their clothes" and described participants' clothing as "fresh set of clothes" and "street clothes;" (2) the investigator did not test for breakthrough and it was not ensured that collected material was not lost from the medium during sampling; and (3) calibration data for air sampling pumps was not provided and it is not indicated whether the air flow changed and the mean flow was used for all calculations.

The following additional items of concern have been noted:

The field fortification samples were prepared using liquid disulfoton. Although it is difficult to prepare granular field spikes, there is no known way to compare the recovery results to recoveries of a granular formulation. The significance of this difference is therefore unknown.

EPA provided the registrant with comments on study outlines submitted to the Agency. The following comment was not fully addressed in the conduct of the study, as both real plants and simulated plants were used:

> Use of Simulated Plants: The Agency prefers that the study use real plants because it is difficult, if not impossible, to tell how closely the "simulated" plant environment reflects what is actually encountered by a homeowner. If the registrant could not find a study site with enough roses or shrubs to treat, the Agency recommended that the study at least include a subset of real plants in established beds to compare the "real" and the "simulated" plants.

The Agency requests a response from the registrant on the above mentioned outstanding issues. However, the data collected in this study are of interim sufficient scientific quality and HED will use the results in the RED. Final acceptability of the study will be determined pending the registrant's response to our concerns.

Versar inc.

MEMORANDUM

TO:	Christina Jarvis	cc:	000.001-01 File Margarita Collantes
FROM:	Diane Forrest/Susan Anderson		Al Nielsen Linda Phillips
DATE:	March 20, 2001		

SUBJECT: Review of *Determination of Dermal (Hand and Forearm) and Inhalation Exposure to Disulfoton Resulting from Residential Application of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care to Shrubs and Flower Beds,* MRID No. 453334-01

This report reviews an applicator exposure study, *Determination of Dermal (Hand and Forearm) and Inhalation Exposure to Disulfoton Resulting from Residential Application of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care to Shrubs and Flower Beds*, submitted by Bayer Corporation. A summary of the study and its general accordance with the U.S. EPA Series 875 Guidelines is provided. The following information may be used to identify the study:

Title:	*Determination of Dermal (Hand and Forearm) and Inhalation Exposure to Disulfoton Resulting from Residential Application of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care to Shrubs and Flower Beds*, 178 pages
Sponsor:	Wayne Carlson, VP Regulatory Affairs and Product Safety Bayer Corporation 8400 Hawthorne Road Kansas City, MO 64120
Testing Facility:	D. Larry Merricks Agrisearch Inc. 5734 Industry Lane Frederick, MD 21704-7293
Analytical Laboratory:	Michael Williams Horizon Laboratories 1610 Business Loop, 70 West Columbia, MO 65205-3608
Author:	D. Larry Merricks
Report Date:	February 8, 2001
Identifying Codes:	MRID # 453334-01, Agrisearch or Lab. Project ID: 4201; Report No. 110136

EXECUTIVE SUMMARY

The purpose of this study was to quantify potential dermal (forearm and hand) and inhalation exposure for residential applicators of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care®, a granular formulation, which contains 1.04 percent disulfoton as the active ingredient. Disulfoton is a systemic organophosphate insecticide registered for use on agricultural crops (e.g., cereals, potatoes, tobacco, cotton, vegetables) and ornamentals. The maximum application rate for flower beds (4 ounces formulated product per 12 square feet) and for shrubs (4 ounces formulated product per 1 foot shrub height) was used in this study.

The field study was conducted at the Bayer Corporation Research Farm, Vero Beach, Florida. A total of 15 volunteers were monitored using passive dosimetry (hand/forearm wash solutions and personal air monitors). Application of the product was made by pouring the granules into the measuring cup/lid attached to the product package, and then distributing the granules onto the soil around the base of a shrub or onto a flower bed. The granules were then soil-incorporated with a garden rake. Each volunteer applied granular disulfoton around shrubs while wearing gloves and then again without gloves. A total of 60 (i.e., 15 volunteers x 4 exposure scenarios) replicates were monitored. Only exposure data from the 30 replicates who did not wear gloves were reported. The test site was a fallow test field, approximately 1 acre in size. Two sets of sub-plots were established: (1) shrub test-plots, each containing 10 oleander shrubs (approximately 48 inches high); and (2) flower-bed sub-plots, each containing simulated plants, (e.g., 12 to 14 inch high stakes placed on approximately 24 inch centers).

Each volunteer applied approximately 10 pounds of formulated product per application. Shrubs were treated by spreading 16 ounces of granules (i.e., 4 ounces per 1 foot of shrub) in a circle around each shrub's base. The granules were then incorporated into the top 1-2 inches of soil using a new garden rake. Flower beds were treated by sprinkling 4 ounces of granules to each 12 square feet of a total 480 square feet area, and incorporating the product into the top 1-2 inches of soil using a new garden rake.

All of the inhalation exposure data were either non-detect or less than the LOQ. Most of the hand/forearm dermal washing samples returned results greater than the LOQ. Disulfoton residues found on the hand and forearm samples collected from monitoring periods where volunteers did not wear gloves were highest when applying Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care® to shrubs. All of the samples collected while subjects treated oleander shrubs were positive, with residue levels ranging from 1.39 to 36 μg/sample (N=15) and with a mean value of 13.5 μg. Ten of 15 samples collected while subjects treated flowerbeds had results >LOQ, ranging from 1.88 to 20.6 μg/sample with a mean of 5.45 μg. The author speculates "applying and working around the larger plants in the shrub plots, and possibly opening and closing the product container at each shrub increased the hand and forearm exposure as compared to flower bed applications."

The author reported that the time it took to treat shrubs ranged between 18 and 29 minutes. The time that it took to treat flowerbeds ranged between 20 and 40 minutes. Five of these exposure periods exceeded the maximum 29 minutes it took to treat a shrub sub-plot.

The study was conducted in compliance with the major technical aspects of OPPTS Group A: 875.1300, Inhalation Exposure -- Outdoor and 875.1100, Dermal Exposure -- Outdoor, and Series 875 Group B, Part C, as they relate to this study. Reviewers noted the following issues of potential interest in interpreting the results:

- EPA provided the registrant with comments on study outlines submitted to the Agency. The following comment was not addressed in the conduct of the study:

  Use of Simulated Plants: The Agency prefers that the study use real plants because it is

difficult, if not impossible, to tell how closely the "simulated" plant environment reflects what is actually encountered by a homeowner. If the registrant could not find a study site with enough roses or shrubs to treat, the Agency recommended that the study at least include a subset of real plants in established beds to compare the "real" and the "simulated" plants.

- For the first three days of exposure monitoring, wind speeds ranged between 4.2 and 8.9 mph. Therefore, conditions were generally windy.

- The test sites were irrigated once the evening prior to each day's exposure monitoring, and again during the lunch break on the first day of exposure monitoring. Sprinkler irrigation was used, and 0.5 inches of water was applied to maintain a packed surface and minimize dust cross-contamination. This is not considered appropriate for a handler exposure study because it may have decreased handler pesticide exposure and may not be representative of typical residential handler behavior.

- There were a total of 60 samples collected for inhalation exposure, and 60 samples collected for dermal exposure, reflecting 15 volunteer subjects, applying disulfoton to both shrubs and flowers bed test plots, with and without gloves. Only the 30 samples, for the inhalation exposure, and 30 samples, for the dermal exposure, representing the "no glove" scenario were reported. All data should have been reported, especially the inhalation exposure samples, which would not have been affected by the use of gloves.

STUDY REVIEW

Study Background

The purpose of this study was to quantify potential dermal (forearm and hand only) and inhalation exposure for residential applicators of Bayer Advanced Garden 2-in-1 Systemic Rose and Flower Care®, a granular formulation, containing 1.04 percent disulfoton as the active ingredient. The CAS name for disulfoton is O,O-diethyl-S-[2-ethylthio)ethyl]-phosphorodithioate, and the CAS No. is #298-04-4. Disulfoton is a systemic organophosphate insecticide registered for use in agricultural crops (e.g., cereals, potatoes, tobacco, cotton, vegetables) and ornamentals.

Exposure monitoring took place on four days: October 23, 24, 25, and 26, 2000. Sample analyses were complete by December 16, 2000.

Attestations

The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10 (d)(1)(A), (B), or (C). The study sponsor and author attested that the study was conducted according to current EPA FIFRA Good Laboratory Practice Standards (40 CFR Part 160). There was one notation to the effect that a pocket penetrometer (used to gauge the degree of soil compaction in the test plots) could not be calibrated. A Quality Assurance Statement was included covering: test procedures, raw and final data review, draft and final report.

Test Plots

The field study was conducted at the Bayer Corp. Research Farm, Vero Beach, Florida. The test site a one acre fallow test field, was disked and prepared in early September 2000. The exact soil type was not reported, but the soil was reported to be sandy.

Two sets of sub-plots were established, one planted with oleander shrubs and the other containing simulated plants. There were 32 shrub test-plots, each measuring 3 feet by 39 feet, and each containing 10 oleander shrubs which were approximately 48 inches high. The shrubs had been planted approximately 33 days prior to exposure monitoring. Each shrub test plot was separated from the next test plot by at least 4 feet to minimize cross contamination.

Likewise, there were 32 flower beds, each measuring 480 square feet (4 feet by 120 feet). Each sub-plot contained simulated plants, that is, 12 to 14 inch high stakes placed on approximately 24 inch centers. The beds were not cultivated for 30 days prior to the exposure monitoring. The flower beds had enough separation between beds to minimize cross contamination.

A pocket penetrometer was used to collect soil compaction measurements. The soil was relatively uniform throughout; the compaction ranged between 0.75 and 1.25 tons / square foot.

Replicates

This study collected hand and forearm dermal exposure data and inhalation exposure data from volunteers applying granular disulfoton around shrubs, and to flower beds. The product was applied by pouring the granules into a measuring cup/lid, sprinkling onto the soil, and soil-incorporating with a garden rake. There were 15 volunteer subjects, each monitored for 4 exposure periods. Sampling included 30 replicates collected during gloved hand application, and 30 replicates collected during applications made without the use of protective gloves. Only exposure data from the 30 replicates who did not wear gloves were reported.

Volunteers ranged in age from 20 to 73 years old, had 0 to 40 years experience gardening, and worked from 18 minutes to 50 minutes during each application. There were nine female and six male applicators. Information on each individual volunteer such as height, weight, age, sex, and years experience using residential pesticide products may be found on page 16 of the Study Report.

Work Activities

Each of the 15 volunteers was monitored for both inhalation and hand/forearm dermal exposure at 4 sampling times on the same day (total number of replicates = 60). Each of the 2 use pattern applications (rose bushes/shrubs and flower beds) was conducted by volunteers wearing gloves. Then the same use pattern applications were conducted by the same volunteers without gloves. Four volunteers were monitored on each of the first three days, followed by the monitoring of three volunteers on the fourth day. Prior to each exposure period, volunteers washed their hands and arms with soap and water. Volunteers were asked to wear a fresh set of clothes to minimize possible contamination. For the first three sessions, volunteers wore new pairs of Tyvek® pants over their clothes. Due to heat, some of the volunteers did not wear Tyvek® trousers on their fourth application, since their street clothes had been protected during the three prior exposure periods. Only exposure data from the 30 replicates who did not wear gloves were reported.

Essentially, each volunteer carried an unopened 10 pound container of 1 percent disulfoton granules to the application location. The measuring cap/lid was removed, and the desired amount poured into the cap. Shrubs were treated by spreading 16 ounces of granules (i.e., 4 ounces per 1 foot of shrub) in a circle around each shrub's base. The granules were then incorporated into the top 1-2 inches of soil using a new garden rake. The applicator then carried the product container to the next shrub and repeated the procedure (pouring, sprinkling, incorporating). After all 10 shrubs were treated the applicator replaced the measuring cap onto the container, tightened the cap and returned to the staging area for the hand/forearm wash procedure. Flower beds were treated by sprinkling 4 ounces of granules to each 12 square feet of the flower bed, and repeating the pouring and sprinkling steps until the whole 480 square feet of area was covered. Then the applicators incorporated the granules into the top 1-2 inches of soil using a new garden rake. Finally, each volunteer replaced the measuring cap and returned to the staging area with their closed, empty (or nearly empty) containers. The amount applied was estimated by weighing each container before and after application. Each volunteer applied approximately 10.1 pounds of formulated product per application, or about 40.4 pounds overall for each day.

The study author included a table briefly noting observations made of each worker during each disulfoton granule application (see page 19 of the Study Report). "Some volunteers worked upwind while applying or cultivating the product and did not enter the test plot bedding area, and some worked downwind while applying or cultivating the product or worked in the test plot bedding area. Overall, volunteers were observed working in the test plot beds more when working with the shrubs than during the flower bed applications since they worked around larger plants as opposed to simulated plants. Some volunteers walked in treated beds to rake, at least one volunteer rubbed their eye with their hands. Some volunteers were observed wiping sweat from their face with their forearms. In general, the author stated that it took about 20 percent more time to apply and incorporate disulfoton granules into flower-bed soil.

Meteorology and Irrigation

The test sites were irrigated once the evening prior to each day's exposure monitoring, and again during the lunch break on the first day of exposure monitoring (October 23, 2000). Sprinkler irrigation was used, and 0.5 inches of water was applied to maintain a packed surface and minimize dust cross-contamination.

An onsite weather station was set up at the test site, and recorded hourly average (collected at 1-minute intervals) ambient air temperature, relative humidity, wind speed and wind direction on each

application day. In general, meteorological monitoring was conducted between approximately 8 AM and 4 PM (ending times each day were different). Ambient air temperatures ranged between 69.6°F and 83.3°F, relative humidity ranged between 51.9 and 92.9 percent, and wind speeds ranged between 1.3 mph and 8.9 mph. For the first three days of exposure monitoring, wind speeds ranged between 4.2 and 8.9 mph. Therefore, conditions were generally windy. No historical weather data were provided for review.

Pesticide Use History

Paraquat was applied once to the flower bed plots and Roundup® was applied as needed to both plots, prior to the exposure monitoring dates, to control unwanted vegetation. No other pesticide use history information was provided.

Materials and Application Method

The product used in the study was EPA Reg. No. 3125-517, containing 10 pounds granular product, packaged as a plastic container with a measuring cup/lid. The product contains approximately 1 percent disulfoton active ingredient. The maximum application rate for flower beds (4 ounces formulated product per 12 square feet) and for shrubs (4 ounces formulated product per 1 foot shrub height) was used in this study. Application was made by pouring the product into the measuring cap/lid and then sprinkling around shrubs or on flower-bed test plots, followed by soil incorporation using a garden rake.

Sample Collection

Personal air monitoring samples and hand/forearm wash samples were collected in this study.

1. Inhalation Exposure Samples

Personal air samples were collected from each volunteer using OVS tubes containing two sections (140 mg/270 mg) of XAD-2 resin, connected via plastic tubing to Gilian® air sampling pumps calibrated to an approximate flow rate of 2.0 liters/minute. Pump on- and off-times were recorded. There were a total of 60 breathing zone samples collected, reflecting 15 volunteer subjects, applying disulfoton to both shrub and flower bed test plots, with and without gloves. Again, data for only 30 of the 60 samples were reported.

2. Dermal Exposure Samples

Exposure to the hands and forearms was determined by detergent washed hand and foreaarm solutions collected at the staging area.

One 500 mL aliquot of an aqueous solution of anionic surfactant (i.e. sodium dioctyl sulfosuccinate (OTS) - 0.01 percent w/v in distilled water) was used to wash subjects' hands and forearms. As reported by the author: "The volunteer placed his hands and forearms in and over a metal container while an investigator slowly poured the aliquot of OTS over them ensuring complete contact of all skin surfaces. At the end of sixty seconds of the volunteer scrubbing his/her hands and forearms in the OTS, the solution was carefully poured into a labeled glass jar." There were a total of 60 dermal exposure samples collected, reflecting 15 volunteer subjects, applying disulfoton to both shrub and flower bed test plots, with and without gloves. Data for only 30 of the 60 samples collected overall were reported (i.e., the no glove scenarios).

QA/QC

Sample Handling & Storage

Each jar of OTS skin washing solution was capped with a Teflon® -lined lid, heat sealed in a plastic bag, and stored in freezer conditions until shipment to the laboratory. Each OVS sample was capped in the field at both ends, labeled, placed in a reclosable plastic bag, and placed into freezer storage until shipment to the laboratory. Field freezers ranged in temperature between (-)25.8°C and (-)12.2°C. Samples were packed with shock insulators and shipped frozen on dry ice. Air samples were sent on October 26, 2000, the final sampling day. All samples received by the analytical laboratory were stored in freezers at temperatures ranging between (-)26°C and (-)10°C.

Sample History

A sample history table was not provided. Exposure monitoring took place on four days: October 23, 24, 25, and 26, 2000. The field OVS air samples were received at the analytical laboratory on October 27, 2000. Field dermal wash samples were received at the analytical laboratory on November 7, 2000. Raw data sheets attached to the analytical report included some sample tracking information.

Product Analyses

Each lot of test substance was analyzed for purity and the percentage of active ingredient was verified. The *Certificate of Analysis* was provided as an attachment to the Study Report.

Analytical Methodology

It appears that a proprietary method was used. A copy of the method was not included in the study report.

1. OVS Air Sampling Tubes

   Tube contents were analyzed as a single sample. Disulfoton was desorbed from the tube contents with acetone. The acetone extract was filtered, diluted to an appropriate volume in acetone, and residues quantified via GC/FPD(P).

2. OTS Dermal Washing Samples

   Dermal washing samples were thawed, mixed with an equal volume of methanol (500 mLs), and aliquots were cleaned up on a conditioned C-18 SPE column. The analyte was eluted from the column with acetone. Disulfoton residues were quantified via GC/FPD(P).

Chromatographic conditions are listed on page 80 of the Study Report. The method employed a DB-5MS column (30M x 0.25 mm, 0.25 μM film thickness). Retention time for disulfoton was about 6.7 minutes. Calibration standards were run with each set, at levels ranging between 5 ng/mL and 250 ng/mL. Data were collected using the Chrom Perfect for Windows® (CPWIN) data acquisition system. Data were imported into Quattro Pro® spreadsheets and calculations were performed using Horizon's LINCURV4® calculation program, which prepares standard curves of response vs. ng/mL using least squares regression. This system was validated on each computer with a model data set prior to each day's run.

Limits of Detection (LOD) & Limits of Quantitation (LOQ)

The LOD was not defined. The reported LOQs were 0.3 μg/air sampling tube, and 1.5 μg/dermal wash sample. The basis for the determination of LOQ was not reported.

Concurrent Laboratory Recovery

Field samples were analyzed in sets containing from 12 to 20 samples each. Laboratory controls were included in each set. These fortified controls were fortified at 4 levels as follows: untreated, LOQ, 10X LOQ and 100X LOQ. A summary of the results is presented on page 92 of the Study Report. The overall mean percent recovery of concurrent laboratory fortifications from OVS air sampling tubes was 99.9 ± 6.42 percent (N=15). The overall mean percent recovery from hand/forearm wash solution was 99.5 ± 9.15 percent (N=24).

Five out of the 8 untreated control air sampling tube samples contained apparent disulfoton residues greater than zero. The residues were less than 10 percent of the LOQ, and the authors state that this residue had a negligible effect on recoveries at any level. Laboratory recovery samples, but not field fortification samples, were corrected for residues found in the companion untreated control samples. No residue in any field sample was corrected for laboratory fortification recoveries.

No disulfoton residues were detected in any of the untreated hand/forearm wash control solutions.

Field Fortification Recovery

Fortified disulfoton solutions and pre-fortified sorbent OVS tubes were prepared by Horizon Laboratories, and then shipped on dry ice overnight to the field facility, where they were also kept frozen.

Field-fortified controls were prepared once each day of exposure monitoring (i.e., four times). They were prepared at the test site staging area, near to the test sites, but away from possible contamination. Specifically, a vial of fortification solution was uncapped and the entire vial (contents plus container) was dropped into a 500 mL aliquot of OTS solution. Pre-fortified OVS air sampling tubes were brought to ambient temperature in the field, connected to a multiport pump and manifold system and the pump was run for the approximate length of a replicate exposure period at 2.0 liters per minute.

Five replicates of each exposure matrix were fortified on each of the four monitoring days, at three fortification levels. For dermal wash samples, the fortification levels were 1.5, 15, and 150 μg/sample, and for the air samples the fortification levels were 0.3, 3 and 30 μg/sample. The field fortification samples were packaged, stored, and shipped under the same environmental conditions as the field samples.

For air samples, the overall average fortified field recovery was 98.2 ± 6.32 percent (N=62) with no apparent differences in mean recoveries between days or fortification levels. Table 1 summarizes field recoveries by fortification level. No measurable disulfoton was measured in any field fortification untreated control sample except for one sample which had a reading of 0.022 μg (<LOQ).

For hand/forearm wash samples collected from volunteers who did not wear gloves, 5 of 30 samples were less than LOQ. The highest level of disulfoton found in any sample was 36 μg/sample. Therefore, the fortification levels analyzed covered the full range of field sample levels. Overall field fortified recovery for these samples was 99.4 ± 7.95 percent (N=36) with no apparent differences in recovery values between days. As noted by the author, there was a slight trend towards increased mean recovery values as the disulfoton

concentration increased, however, all recovery values were well within guideline specifications (i.e., 70 to 120 percent). Table 1 presents a summary of field fortifications recoveries by fortification level. No measurable disulfoton residue was measured in any field fortification untreated control hand wash sample.

Table 1. Summary of Field Fortification Recoveries

Sample	Fortification Level	Average Recovery (Percent)			
		Day 1	Day 2	Day 3	Day 4
Air Sampling Tubes	0.3 μg	95.7 ± 5.26 (N = 5)	96.0 ± 4.38 (N = 3)	97.2 ± 4.54 (N = 3)	98.4 ± 2.86 (N = 3)
	3.0 μg	105 ± 2.60 (N = 5)	103 ± 3.45 (N = 3)	103 ± 2.48 (N = 3)	99.9 ± 0.500 (N = 3)
	30 μg	94.0 ± 11.4 (N = 5)	91.8 ± 7.42 (N = 3)	102 ± 2.13 (N = 3)	93.5 ± 2.88 (N = 3)
Dermal Wash Solution	1.5 μg	92.1 ± 5.65 (N = 3)	96.8 ± 2.75 (N = 3)	91.8 ± 5.14 (N = 3)	92.0 ± 3.69 (N = 3)
	15 μg	104 ± 2.92 (N = 3)	104 ± 4.70 (N = 3)	94.3 ± 16.1 (N = 3)	97.7 ± 9.96 (N - 3)
	150 μg	107 ± 0.907 (N = 3)	108 ± 1.75 (N =3)	101 ± 4.09 (N =3)	105 ± 2.90 (N = 3)

Storage Stability Recovery

No storage stability samples were prepared. Instead, the authors relied on field recovery samples, which were handled and analyzed in conjunction with the field test samples.

Results

Tables 2 and 3 summarize the exposure monitoring results by replicate for application to shrubs and flower beds, respectively. All of the inhalation exposure data were either non-detect or less than the LOQ. Possible reasons for these finding include: 1) disulfoton is not volatile, and the formulation used was granular; 2) samples were collected on sorbent tubes; 3) the exposure periods were very brief, ranging between 18 and 38 minutes; and 4) samples were collected outdoors under rather windy conditions and small air volumes were collected, ranging between 36 and 76 liters per sample.

Table 2. Summary of Exposure Data By Replicate - Shrub Application						
Volunteer	**Body Weight (kg)**	**Formulation Applied (lb ai) rounded**	**Hours Worked**	**Air Volume (Liters)**	**Inhalation Exposure (μg/sample)**	**Hand/Forearm Exposure (μg/sample)**
1	68	0.1	0.35	42	ND	13.40
2	66	0.1	0.30	36	<LOQ	30.20
3	114	0.1	0.32	38	<LOQ	18.70
4	64	0.1	0.38	46	<LOQ	15.00
5	66	0.1	0.45	54	ND	3.53
6	73	0.1	0.40	48	ND	17.20
7	57	0.1	0.45	54	<LOQ	4.51
8	55	0.1	0.38	46	<LOQ	1.63
9	59	0.1	0.38	46	ND	9.46
10	70	0.1	0.37	44	ND	36.00
11	80	0.1	0.35	42	<LOQ	4.11
12	132	0.1	0.35	42	ND	24.50
13	66	0.1	0.40	48	<LOQ	1.39
14	102	0.1	0.48	58	ND	6.99
15	77	0.1	0.37	44	ND	16.10
Arithmetic Mean	-	-	-	-	-	12.9
Standard Deviation	-	-	-	-	-	10.0
Coefficient of Variance	-	-	-	-	-	78 percent

LOQ = 0.3 μg/ air sampling tube (½ LOQ or 0.15 μg was assigned to values <LOQ or ND)

Table 3. Summary of Exposure Data By Replicate - Flower Bed Application						
Volunteer	**Body Weight (kg)**	**Formulation Applied (lb ai) (rounded)**	**Hours Worked**	**Air Volume (Liters)**	**Inhalation Exposure (μg/sample)**	**Hand/Forearm Exposure (μg/sample)**
1	68	0.1	0.37	44	<LOQ	<LOQ
2	66	0.1	0.42	50	<LOQ	2.94
3	114	0.1	0.33	40	<LOQ	1.88
4	64	0.1	0.37	44	<LOQ	20.60
5	66	0.1	0.63	76	<LOQ	8.45
6	73	0.1	0.57	68	<LOQ	<LOQ
7	57	0.1	0.53	64	<LOQ	<LOQ
8	55	0.1	0.67	80	<LOQ	<LOQ
9	59	0.1	0.47	56	<LOQ	4.24
10	70	0.1	0.40	48	<LOQ	5.00
11	80	0.1	0.42	50	<LOQ	12.10
12	132	0.1	0.43	52	<LOQ	3.16
13	66	0.1	0.45	54	<LOQ	11.90
14	102	0.1	0.52	62	<LOQ	<LOQ
15	77	0.1	0.45	54	<LOQ	8.20
Arithmetic Mean	-	-	-	-	0.15	5.4
Standard Deviation	-	-	-	-	-	5.8
Coefficient of Variance	-	-	-	-	-	106 percent

LOQ = 0.3 μg/ air sampling tubes (½ LOQ or 0.15 μg was assigned to values <LOQ)
LOQ = 1.5 μg/dermal wash (½ LOQ or 0.75 μg was assigned to values <LOQ for calculation of mean)

Most of the hand/forearm dermal washing samples returned residue levels greater than the LOQ. All of the samples collected while subjects treated oleander shrubs were positive, ranging from 1.39 to 36 μg/sample (N=15). Ten of 15 samples collected while subjects treated flowerbeds were positive. For those 10 positive samples, values ranged between 1.88 to 20.6 μg/sample. The author reported that the time it took to treat shrubs ranged between 18 and 29 minutes. The time that it took to treat flowerbeds ranged between 20 and 40 minutes; five of these exposure periods exceeded the maximum 29 minutes it took to treat a shrub sub-plot.

Tables 4 and 5 present the exposure data in unit exposure values, normalized to pounds active ingredient per amount handled per sampling period, and pounds active ingredient per amount handled per hour, and pounds active ingredient per amount handled per kilogram body weight per sampling period. These values were calculated by Versar. An inhalation unit exposure volume was not determined for shrub plot applications because no numerical value was assigned in the report to non-detect values. In the risk assessment accompanying the Study Report (MRID 453334-02) the registrant using a value of 30 percent of the LOQ (0.09 μg) for non-detects.

Table 4. Unit Exposure Values - Shrubs						
Type	**mg/lb ai**		**mg/hour[e]**		**mg/kg/sampling period[f]**	
	Dermal[a,d]	**Inhalation[b,c]**	**Dermal[a]**	**Inhalation[b]**	**Dermal[a]**	**Inhalation[b]**
Arithmetic Mean	0.14	0.013	0.038	0.0004	0.0002	0.0000055
Std. Dev.	0.11	0.000079	0.032	0.00005	0.00018	0.0000013
Geo Mean	0.092	0.013	0.024	0.0004	0.00013	0.0000053
25th %tile	0.043	0.012	0.011	0.00038	0.000061	0.0000051
75th %tile	0.18	0.013	0.051	0.00043	0.00024	0.0000062
90th %tile	0.27	0.013	0.086	0.00045	0.00049	0.0000070
95th %tile	0.32	0.013	0.098	0.00048	0.00053	0.0000073
99th %tile	0.35	0.013	0.10	0.0005	0.00056	0.0000075

LOQ = 0.3 μg/air sampling tube

LOQ = 1.5 μg/dermal wash

A respiratory rate of 16.7 L/min was assumed, based on the draft NAFTA recommended inhalation rates.

[a] The unit exposure value is base on data where some values are <LOQ

[b] The unit exposure value is based on data where all values are <LOQ.

[c] Inhalation unit exposure (mg/lb ai) =[residue (μg*0.001) / air volume (l)]* 16.7 l/min(minute volume of human) * minutes worked / pounds ai handled.

[d] residue (μg*0.001)/pounds ai handled

[e] residue (μg*0.001)/hours worked

[f] residue (μg*0.001)/body weight/hours worked

Table 5. Unit Exposure Values - Flower Beds						
Type	**mg/lb ai**		**mg/hour[e]**		**mg/kg/sampling period[f]**	
	Dermal[a,d]	**Inhalation[b,c]**	**Dermal[a]**	**Inhalation[b]**	**Dermal[a]**	**Inhalation[b]**
Arithmetic Mean	0.054	0.013	0.013	0.00033	0.000079	0.0000045
Std. Dev.	0.058	0.0000829	0.015	0.000065	0.000087	0.0000011
Geo Mean	0.030	0.013	0.0066	0.00033	0.00044	0.0000044
25th %tile	0.0075	0.012	0.0017	0.00029	0.00015	0.0000038
75th %tile	0.083	0.013	0.016	0.00037	0.00012	0.0000054
90th %tile	0.12	0.013	0.028	0.00041	0.00017	0.0000057
95th %tile	0.15	0.013	0.037	0.00042	0.00022	0.0000061
99th %tile	0.19	0.013	0.052	0.00045	0.0003	0.0000063

LOQ = 0.3 μg/air sampling tube

LOQ = 1.5 μg/dermal wash

A respiratory rate of 16.7 L/min was assumed, based on the draft NAFTA recommended inhalation rates.

[a] The unit exposure value is base on data where some values are <LOQ

[b] The unit exposure value is based on data where all values are <LOQ.

[c] Inhalation unit exposure (mg/lb ai) =[residue (μg*0.001) / air volume (l)]* 16.7 l/min(minute volume of human) * minutes worked / pounds ai handled.

[d] residue (μg*0.001)/pounds ai handled

[e] residue (μg*0.001)/hours worked

[f] residue (μg*0.001)/body weight/hours worked

Compliance Checklists

Compliance with OPPTS Series 875, Occupational and Residential Exposure Test Guidelines is critical. The itemized checklist below outlines compliance with the major technical aspects of OPPTS Group A: 875.1300, Inhalation Exposure -- Outdoor and 875.1100, Dermal Exposure -- Outdoor, as they relate to the study.

- *Typical end use product of the active ingredient used.* This criterion was met.

- *End use product handled and applied using recommended equipment, application rates, and typical work practices.* It is uncertain whether this criteria was met. The application technique employed in this study might not represent the typical method of application of granular pesticide to rose bushes or shrubs. It is likely that a homeowner could apply the product while on hands and knees and reaching underneath foliage (with hands or hand trowel) to reach the base of the plant. If this work practice was assessed, additional dermal monitoring would be required in order to adequately characterize potential dermal exposure (i.e., exposure to knees, upper and lower legs, and feet).

- *A minimum of five replicates each at a minimum of three different sites are to be employed.* This criterion was met.

- *Dermal and/or inhalation exposure should be monitored by validated methodologies.* This criterion was met.

- *There should be a minimum of one field-fortified sample per worker per monitoring period for each fortification level, plus unfortified field blanks.* This criterion was met.

- *The efficiency of extraction of hand rinses conducted in one solvent with subsequent partition into a second solvent for analysis should be determined*. This criterion was met. Method validation, laboratory and field-fortified recovery values were satisfactory.

- *The stability of the analyte of interest in the medium of interest must be determined*. This criterion was met as demonstrated by satisfactory field fortification recoveries.

- *The following information should be reported for agricultural applications, yards, gardens: (1) description of the crop, plot size, row spacing; (2) description of application (including rate, type of formulation, tank capacity, type of carrier, final mix concentration, total pounds active ingredient applied or mixed); (3) description of application equipment (type, model); (4) weather data: relative humidity, wind speed, wind direction, and temperature; (5) work activity monitored; (6) exposure observations; (7) exposure time*. These criteria were met.

- *After collection, field samples should be stored immediately in a freezer pending further treatment.* This criterion was met.

- *A sample history sheet should be included in the report, tracking sample number, date of collection, date of extraction, date of analysis, and identification of who participated in each stage*. This criterion was partially met. While a history sheet as such was not provided, most of the information was available in the report.

- *Clothing worn by each study participant should be thoroughly described.* This criterion was not met. The author states that "for the first three sessions, volunteers wore new pairs of Tyvek® pants over their clothes". The other clothing worn by study participants (e.g., long sleeved vs. short sleeved shirt) is described only as "fresh set of clothes" and "street clothes".

- *Quantity of active ingredient handled and duration of monitoring period should be reported for each replication.* This criterion was met.

- *Testing should include at least one field fortification sample per worker per monitoring period per fortification level for each matrix should and at least one field blank per worker per monitoring period for each matrix.* This criterion was met.

- *Efficiency of extraction in laboratory provided as a mean plus or minus one standard deviation.* This criterion was met.

- *The analytical method for inhalation monitoring should be sufficiently sensitive so that, coupled with the trapping and extraction procedures chosen, it is capable of measuring exposure to 1 µg/hour (or less)*. This criterion was met. The LOQ for the method was 0.3 µg/sample. Samples were collected on OVS-XAD sorbent tubes. Exposure periods ranged between 18 and 38 minutes, and were collected at 2 liters/minute, yielding sample volumes, ranging between 36 and 76 liters per sample.

- *To ensure that collected material is not lost from the medium during sampling, the investigator should also test for breakthrough*. This criterion was not met. The investigator did not test for breakthrough to ensure that collected material was not lost.

- *If trapping media are to be stored after exposure, a test for the storage stability of the compound should be documented. The time periods for storage are to be chosen so that the longest corresponds to the longest projected storage period for field samples*. This criterion was met. Field-fortified recovery samples analyzed at about the same time as the field samples indicated satisfactory storage stability.

- *Applicator's inhalation exposure should be measured with battery-powered personal monitoring pumps capable of producing an airflow of at least 2 liters per minute and pump batteries should be capable of sustaining maximum airflow for at least 4 hours without recharging.* This criterion was met.

- *The intake tube of any pump-powered sampler unit should be positioned so that the opening is downward. The intake tube should be placed as near as possible to the nose level of the test subject*. It is not known whether these criteria were met, as these details were not reported. The author did, however, state that monitoring occurred in the breathing zone.

- *Calibration data for air sampling pumps should be provided. If the air flow has been found to change, the mean flow should be used for all calculations.* This criterion was not met. Calibration data for air sampling pumps was not provided.

The following additional items of concern have been noted:

The field fortification samples were prepared using liquid disulfoton. Although it is difficult to prepare granular field spikes, there is no known way to compare the recovery results to recoveries of a granular formulation. The significance of this difference is therefore unknown.

EPA provided the registrant with comments on study outlines submitted to the Agency. The following comment was not fully addressed in the conduct of the study, as both real plants and simulated plants were used:

> Use of Simulated Plants: The Agency prefers that the study use real plants because it is difficult, if not impossible, to tell how closely the "simulated" plant environment reflects what is actually encountered by a homeowner. If the registrant could not find a study site with enough roses or shrubs to treat, the Agency recommended that the study at least include a subset of real plants in established beds to compare the "real" and the "simulated" plants.